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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,092	10/19/2001	S. Rao Cherukuri	24222-X2	6756

7590 03/09/2005

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,092	CHERUKURI ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-10 and 14-42* is/are pending in the application.

4a) Of the above claim(s) *14,15,19-28 and 31-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-10,16-18,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks filed 01/14/05. Claims 1, 6-10 and 14-42 are pending and of these, claims 14, 15, 19-28 and 31-47 are withdrawn from consideration. Claim 18 was not withdrawn from consideration. It was claim 19 that was withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 01/14/05 has been entered.

Status Identifier:

Applicants have identified the withdrawn claims as "withdrawn from consideration." The proper status identifier is withdrawn. It is thus respectfully asked of applicants to use the proper status identifiers on all claims in all future listing of claims.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 6-10, 16-18, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour (US 6,352,721).

Faour discloses the delivery of amitriptyline, fluoxetine, sertraline and venlafaxine tricyclic antidepressant agents (column 14, lines 55-60). Faour discloses that for oral, buccal and sublingual administration, the delivery device is formulated in the form of caplet or tablet (column 17, lines 57 and 58). Hydroxyethylcellulose (column 9, line 13), carboxymethylcellulose sodium (column 10, line 50), magnesium or calcium stearate (column 10, lines 41 and 42), oils, fatty acid glycerides, emulsifying agents, flavor agents, coloring agents and disintegrants (column 11, line 49 to column 12 line 39) are included in the composition. Aspirin and cisapride are also deliverable by the delivery device of Faour (column 5, lines 59 and 60). Faour exemplifies the formulation with cisapride in example 1, and in that example silicon dioxide and magnesium stearate are included in the formation of the granules. Claim 29 recites migraine therapeutic that is further limited to amitriptyline, aspirin and varapamil and others by claim 30.

The difference between Faour and the instant claims is that the prior art Faour is silent in the length and diameter of the caplet. Caplets by their nature and design have dimensions of length and diameter and it is within the purview of the person of skill or ordinary skill in the art to have the capacity to measure the parameters of length and diameter. Although, applicants would state that the diameter and length of the caplet: a) "aid in providing a controlled or extended release product with high levels of active ingredients and helps produce a product with uniform active ingredient content throughout," b) "the size of the caplet also helps withstand mechanical pressure both in the processing of the caplet and the chewing of the product in the

mouth so that the active ingredients are released in the stomach of the consumer," c) "the smaller size of the product allowed for better controlled release of the active ingredients," d) "the smaller size results in a different erosion pattern, yet the release of the active ingredient is better controlled through the small size of the delivery medium," it is noted that there is no comparable data to demonstrate the above assertions. In the absence of a showing, the recited length and diameter of the caplet does not patentably distinguish the claimed caplet over the caplet of the prior art. The showing provided is not commensurate with caplet having length of from about 1 mm to about 7 mm. Comparing capsule and tablet and caplet is not commensurate when the claim is directed to caplet of certain range of length. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the caplet formulation of Faour where the formulation comprises antidepressant, erodible polymer and lubricants. One having ordinary skill in the art would have been motivated to prepare the caplet of Faour with the expectation of orally delivering the antidepressants.

Response to Arguments

Applicants argue that the Faour reference is an osmotic dosage form that includes membranes and osmotic pumping passageway and the Faour reference is "totally irrelevant to the claimed invention" and Faour would not lead the person of ordinary skill in the art to applicants claimed invention, which is an extended or controlled release encapsulated product. Secondly, applicants argue that Faour does not disclose the size of the caplet, an important feature of applicants claimed dosage form. To support this position, applicants tested in vitro dissolution of controlled release venlafaxine formulation in capsule containing granules, 11 mm

tablet and 3 mm caplet. The test concluded that the smaller size caplet provides greater control over the release of the active ingredient.

3. Applicants' arguments filed 01/14/05 have been fully considered but they are not persuasive.

Faour's device is controlled release dosage form and comprising an active agent and erodible polymer and the dosage form is a caplet (or tablet) just as the instant claim 1. Applicants generic claim does not exclude the presence of passageway. The difference between Faour and the instant generic claim is the size of the caplet. Thus Faour is relevant to the broad generic claim.

Response to applicants' dissolution test

The generic claim 1 requires the length of the caplet to be from about 1 millimeter to about 7 millimeter. Applicants do not show dissolution data of the limits of the recited length of from about 1 millimeter to about 7 millimeter. There is also no showing of caplets having lengths 1 millimeter and less and 7 millimeter and greater. Comparing caplet with tablet and capsule is not commensurate with the scope of the claims. A comparison of caplets having lengths outside the recited range and within the recited range would appear to be appropriate showing. Several points may be needed to show that from about 1 mm to about 7 mm is critical over other caplet lengths. Caplets by their very nature have the dimensions of length. Thus, applicants have not shown that caplets having lengths of from about 1 mm to about 7 mm has unusual delivery of the active agent over caplets having lengths $\leq$ 1 mm and $\geq$ 7 mm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600